

EXHIBIT 31

From: Van Duren, Al
To: Andrew, Christopher
CC: Scott, Mark
Sent: 4/10/2006 3:31:36 PM
Subject: WCR Question

Hello Christopher,

You made the following comment in the WCR:

"I have had a number of inquiries of late regarding the possibility of surgical site infection as a result of Bair Hugger usage (particularly Adult Underbody). Research available from the Critical Care forum (2003) is not considered to be a large enough study group. Have we considered a more in-depth clinical review of this issue? Placing the underbody blanket on a large number of patients in an active CVOR could provide a more substantial position when it comes to the question of whether Bair Hugger is potentially adding a risk for surgical site infection."

The most important reason that we haven't studied this question has to do with the large number of subjects required to answer the question. Assume that the baseline surgical infection rate is approximately 3% and we think that using our blanket might halve the rate to 1.5%. A properly powered study to confirm our hypothesis would require 1803 subjects per group, or a total of 3606 patients. Typical costs for a study of this complexity run approximately \$1500.00 per patient, which means that the least expensive study we could conduct would cost the company approximately \$6,000,000.00. The study would take several years to complete and at the end it might not show a significant difference. In fact, even if there were a difference as large as the hypothesized estimate, we'd miss detecting it 20% of the time. Moreover, if there isn't any actual difference, we would incorrectly conclude that there is one at least 5% of the time. I don't think that promoting a study like this would be a good career move for me.

People are frequently astonished at the large number of subjects required to conduct a scientifically valid and ethically sound study. This is especially true when one is measuring an outcome that has a low event rate like surgical site infections. This is the major reason that we measure surrogate outcomes like temperature, which require many fewer patients to confirm or refute a hypothesis.

I hope that this helps,

Al

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